REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1 and 7-20 are requested to be canceled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 2-6 are currently amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 2-6 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Objections

Claims 2 and 3 are objected to because they are directed to non-elected inventions.. Office Action, p. 3. Applicants have amended the claims to the elected subject matter and respectfully request reconsideration and withdrawal of the objection.

b. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1, 4, and 8 are rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. Office Action, p. 10. Applicants believe the Office inadvertently rejected claim 8 (which was withdrawn by the Examiner) instead of claim 6 (containing the

language at issue). Applicants have canceled claim 1 and the rejected portion of claim 4. Regarding claim 6, Applicants believe a person of ordinary skill in the art would understand these claims as describing sequences which downregulate or upregulate the expression of an operably linked gene. Applicants respectfully request reconsideration and withdrawal of the rejection.

c. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph for lack of written description as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Office Action, pp. 4-5.

The Federal Circuit has recently clarified the law regarding written description in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed.Cir. 2006). Specifically, the court held:

> 1) examples are not necessary to support the adequacy of a written description,
> 2) the written description standard may be met even when actual reduction to practice is absent; and
> 3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure

Id., at 1366. The Federal Circuit clarified issues particularly relevant for this application. First, the absence of examples does not render written description inadequate. The court favorably cites *LizardTech Inc. v. Earth Resource Mapping, PTY Inc.*, 424, F.3d 1336 (Fed.Cir. 2005) explaining that the specification is written for a person skilled in the art and it is unnecessary to spell out every detail of the invention, only enough is required to convince a person of skill in the art that the inventor possessed the invention and to enable the person to make and use the invention without undue experimentation. Id.

The court further clarifies, as provided in *Capon v. Eshlar*, 418 F. 3d 1349 (Fed.Cir 2005) that the 'written description' requirement implements the principle that a patent must describe the technology to be patented. This requirement is to satisfy the inventor's obligation to disclose the technologic knowledge upon which the application is based and to

demonstrate that the patentee was in possession of the invention. However, the fact that an applicant does not produce the claimed invention is not dispositive of the possession inquiry because an actual reduction to practice is not required for written description. *Faulkner*, at 1366. Proof of reduction to practice is not required in every case. Thus, to the extent that written description requires a showing of "possession of the invention", *Pfaff* makes clear that an invention can be complete even when an actual reduction to practice is absent. 525 U.S. 55 (1998). The logical predicate of "possession", is "completeness." *Faulkner*, at 1367.

With regards to recitation of known structure, Faulkner explicitly holds, "it is the binding precedent of this court that *Eli Lilly* does not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." Id. In the current application, Applicants have sufficiently disclosed the invention to meet the written description requirement in line with the reasoning provided by the Federal Circuit.

Applicants have amended claim 2 to recite a composition comprising SEQ ID No: 47 and functional variants. In addition, claim 3 has been amended to recite functional variants that are at least 90% identical to SEQ ID No: 47. Applicants have provided the sequence for SEQ ID No: 47 in the application and Examples incorporating this sequence. Descriptions of functional variants are found throughout the application, for example, on pages 43-44. Methods for making and using nucleic acids, such as the functional variants, complements, or reverse sequences, are well known to one of skill in the art and are described in the application, for example, on pages 44-46 and in the Examples. A person of skill in the art could readily identify if a sequence is 90% identical to the provided SEQ ID No: 47.

The above description, meets the standard currently employed by the Federal Circuit. The application provides extensive disclosure about the technology and background of the vascular preferred promoters and methods of analyzing sequences. These disclosures would satisfy a person of skill in the art that the technology is adequately described in the application. SEQ ID No: 47 is provided in the application. Examples for each and every sequence are not required claimed is not required by the Federal Circuit. A person of skill in the art would understand from the examples that SEQ ID No: 47 was isolated by the inventor

and that the production of functional variants was adequately described to indicate that the inventors had a complete and described invention regarding the other claimed sequences. There is no rule that every sequence must be provided in the application when a person of skill in the art could readily identify the invention claimed. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Applicants respectfully request reconsideration and withdrawal of the rejection. The Office asserts that the Application is enabling for an isolated nucleic acid molecule of SEQ ID NO: 47, but is allegedly not enabling for the other sequences described. Office Action, pp. 6-7.

Applicants believe "[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP, 8 th ed. Rev.2, 2164.01. See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies , Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As noted above, Applicants have amended claims 2-6 to recite compositions of SEQ ID No: 47 and related sequences. The Office has conceded that the application is enabled for SEQ ID No: 47. Office Action, p. 6. As the Examples provide the necessary steps for enabling the use of SEQ ID NO: 47, the Examples also provide the enabling disclosure for other sequences described in the application. In fact, the specification provides data for over 50 sequences. See Examples 1-9. These results indicate that the use of the claimed sequences was sufficiently described and the steps are able to predictably provide information regarding the sequences. A person of skill in the art reading the specification can readily identify the sequences described in the claims and make the sequences using techniques provided in the specification or known to one of skill in the art. The sequences can then be tested using the procedures outlined in the specification and enabling for over 50 different sequences described in the application. These findings indicate the enablement of the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

d. Claim Rejections - 35 U.S.C. § 102

Claims 1, 5 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bevan, et al. Office Action, p. 11. Applicants have canceled claim 1 and amended claims 5 and 6. Bevan describes a nucleic acid molecule from the PAL gene. Id. The current claims are drawn to SEQ ID No: 47 and functional variants thereof. As Bevan does not describe the currently claimed invention, Bevan cannot serve as the basis for § 102 rejection.

Claim 4 is rejected under 35 U.S.C. § 102(b) as being anticipated by Polvere, et al. Office Action, p. 11. Applicants have amended the claims to cancel section (c) and believe this amendment obviates the rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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